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Ureteral Obstruction: Is the Full Metallic Double-Pigtail Stent the Way to Go?

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Abstract

Background: The Resonance metallic ureteral stent (Cook Medical, Bloomington, Indiana, USA) has been introduced for the management of extrinsic-etiology ureteral obstruction for time periods up to 12 mo.
Objective: The current study aims to determine short- and medium-term effectiveness of the Resonance stent in malignant and benign ureteral obstruction.
Design, setting, and participants: In total, 50 patients with extrinsic malignant obstruction ($n = 25$), benign ureteral obstruction ($n = 18$), and previously obstructed mesh metal stents ($n = 7$) were prospectively evaluated.
Intervention: All patients were treated by Resonance stent insertion. Twenty stents were inserted in antegrade fashion, and the remaining stents were inserted in a retrograde approach. No patient dropped out of the study. The follow-up evaluation included biochemical and imaging modalities.
Measurements: We evaluated the technical success rate, stricture patency rate, complications, and the presence and type of encrustation.
Results and limitations: The technical success rate of transversal and stenting of the strictures was 100%. In 19 patients, balloon dilatation was performed prior to stenting. The mean follow-up period was 8.5 mo. The stricture patency rate in patients with extrinsic malignant ureteral obstruction was 100% and in patients with benign ureteral obstruction 44%. Failure of Resonance stents in all cases of obstructed metal stents was observed shortly after the procedure (2–12 d). In nine cases, stent exchange was demanding. Encrustation was present in 12 out of 54 stents.
Conclusions: The Resonance stent provides safe and sufficient management of malignant extrinsic ureteral obstruction. Resonance stent use in benign disease needs further evaluation, considering the untoward results of the present study.

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1. Introduction

Ureteral obstruction resulting from malignancy or recurrent benign disease is sometimes extremely challenging for the urologist. Percutaneous nephrostomy (PN), polymeric ureteral stents, and metal mesh stents are used with variable success rates for long-term relief of upper urinary tract obstruction. The success rates of retrograde ureteral stenting for intrinsic ureteral and malignant extrinsic obstruction are 88–100% and 56%, respectively. Quality of life (QoL) is negatively affected by the need for frequent stent changes as well as by stent-related symptoms. Polymeric ureteral stents are associated with the highest success rate (98.7%) and significant morbidity [1–6]. Metal mesh stents have been used for long-term drainage in an effort to improve patient QoL, but they are associated with a high rate of migration, stone encrustation, and obstruction resulting from hyperplastic reaction [7,8]. Experience with novel methods for the relief of upper urinary tract symptoms, such as the Detour extra-anatomic stent (EAS; Mentor-Porgés, UK), is limited [9].

The Resonance metallic ureteral stent (Cook Medical, Bloomington, Indiana, USA) has been introduced as a temporary drainage solution (up to 12 mo) for extrinsic ureteral obstruction. The management of malignant extrinsic and benign intrinsic ureteral obstruction has been reported in the literature with promising results [10–12]. In an attempt to clarify the indications for the use of this novel stent, both malignant and benign cases have been included in the current study. In this paper, we present our experience with the Resonance stent for management of patients with ureteral obstruction of malignant and benign etiology in the largest patient population reported to date.

2. Materials and methods

Fifty patients (32 male and 18 female) with a mean age of 65 yr (range: 47–82 yr) who presented with upper urinary tract obstruction were treated with Resonance stent insertion. Our cohort consisted of 25 patients with extrinsic malignant disease obstruction, 18 patients with benign disease obstruction, and 7 patients with a previously obstructed metal mesh stent (Table 1). In four patients, stents were placed bilaterally. Fifty-four ureters were stented totally. Patients had upper tract obstruction or presented with compromised renal function or hydronephrosis that was detected with transabdominal ultrasonography, computed tomography (CT), or intravenous urography. Stent placement was chosen after comprehensive discussion of the alternative therapeutic solutions with each patient. All patients provided informed consent. Inclusion criteria were cases of ureteral obstruction secondary to extrinsic pressure resulting from retroperitoneal or pelvic malignant disease (group A). Moreover, benign strictures in patients unfit to undergo major reconstructive surgery or endoscopic manipulation because of severe comorbidities were included. The latter cases were ureteroileal anastomosis strictures (group B), iatrogenic benign strictures (group D), and renal stone disease (group C). Patients with previously obstructed metal mesh stents (group E) were also included in the study. Patients with height $\leq$ 175 cm were treated with the shorter versions of the Resonance stent (22–26 cm). Patients with height $\geq$ 175 cm were treated with a 28–cm stent.

Routine follow-up appointments included evaluation of complete blood count (CBC), urinalysis, urine culture, serum creatinine levels, and ultrasonography every 4 wk during the first 6 mo and every 3 mo thereafter. All patients received specific instructions to present at our institution in case of symptoms such as ipsilateral flank pain, fever, dysuria, hematuria, or vomiting. In these cases, the follow-up evaluation took place and CT scanning was performed whenever necessary to monitor the upper urinary tract. Failure of the Resonance stent was considered to be inefficient drainage, which was proven by the comparative imaging assessment of the dilatation of the pelvicaliceal system. In cases of bilateral Resonance stent obstruction, serum creatinine levels increased. Resonance stents that failed to alleviate the obstruction were exchanged with polymeric ureteral stents, or the patients underwent percutaneous nephrostomy placement. All stents that indwelled for 14 mo with no signs of obstruction were exchanged.

The Resonance stents were inserted using an antegrade or retrograde technique. Patients presenting with long strictures or strictures of the lower ureter were selected for percutaneous antegrade stent insertion under general anesthesia.

For the antegrade approach, standard PN was performed. Antegrade nephrostomogram followed to define the ureteral anatomy and the exact length and position of the stricture. The stenosed segment was then passed with the use of a 0.035-in guidewire. Dilatation of the stricture with use of a high-pressure balloon catheter (8–10 mm diameter) followed if the stricture was not wide enough to accommodate the introducer sheath before stent insertion. A coaxial system of catheter and sheath was then passed over the wire, including an inner 5F ureteral catheter and an outer 9F introducer sheath. The guidewire and the inner ureteral catheter were then removed, leaving only the tip of the outer sheath in the bladder, and the Resonance stent was pushed through the introducer sheath into the bladder using a plastic pusher at the proximal end. When the distal curl was formed in the bladder, we resisted pushing the proximal end of the stent too far, as there is no retrieval thread or mechanism with this deployment kit. When the proximal end was placed within the collecting system, the introducer sheath was removed over the pusher while holding the pusher in position. When the introducer sheath reached the marked site on the pusher, only the proximal pigtail was left inside the sheath. Further removal of the sheath over the pusher allowed the formation of the final pigtail in the colleting system.

For retrograde stent insertion, with the patient under local or light anesthesia, a similar technique was used, taking care to avoid pushing the proximal end of the stent too far into the ureter. Perioperative prophylaxis with antibiotics was administered in all the cases.

Resonance stent exchange was performed by insertion of a hydrophilic guidewire parallel to the stent that was advanced up to the kidney before stent removal. In the case of failure to pass the wire, the stent was removed and standard stent insertion was repeated as described above.

Table 1 – Summary of disorders treated by the Resonance stent

Groups	Underlying disease	No. of cases
Malignant disease (group A)	Prostate cancer	8
	Colon cancer	4
	Stomach cancer	1
	Gynecologic cancer	7
	Bladder cancer	3
	Lymphoma	2
Benign disease	Ureteroenteric strictures (group B)	6
	Stone disease (group C)	8
	Iatrogenic strictures (ureteroscopic, group D)	4
Previous obstructed metal stent	Ureteroenteric strictures (group E)	7

The study of the phenomenon of encrustation on Resonance stents was performed by scanning electron microscopy (SEM) and energy-dispersive analysis by x-ray (EDAX).

3. Results

The technical success rate of transversal and stenting of the strictures was 100%. Antegrade/percutaneous insertion was performed in 24 cases, and retrograde/cystoscopic insertion in 26 cases. Four patients with malignant disease required bilateral Resonance stent insertion. In 19 patients (35%), balloon dilatation was performed to ease passage of the Resonance stent. No major complications were encountered, and a total of 54 ureters were stented. Additional interventions to achieve stricture patency were not deemed necessary. Mean follow-up was 8.5 mo (range: 4–14 mo). The results are summarized in Table 2. After a mean follow-up time of 11 mo (range: 4–14 mo), all stents in group A achieved stricture patency (100%). The stricture patency rate for benign ureteral obstruction cases was only 44% after a mean follow-up of 6.8 mo. More specifically, the Resonance stent failed to preserve stricture patency in 8 out of 18 cases after a mean follow-up period of 2.6 mo. The above cases included one case with renal stone disease, three cases with ureteroenteric stricture, and four cases with extensive iatrogenic ureteral stricture. In the first case, the stent was heavily covered with encrustation deposits shortly after placement. In the remaining cases, failure was attributed to the development of a hyperplastic reaction that invaded through the coils of the stent and finally led to its occlusion. The latter stents were removed, and the patients were managed using other interventional approaches.

In all seven cases of group E, the Resonance stents failed to alleviate the obstruction, and imaging evaluation revealed increasing dilatation shortly after stent insertion. The cause of obstruction was the hyperplastic reaction expanding through the spiral coil of the stent. The mean time to failure was 7 d (range: 2–12 d). Eventually, insertion of a polymeric ureteral stent was deemed necessary.

Stent-related complications were encountered in six patients who developed macroscopic hematuria, which resolved spontaneously. Additionally, 10 patients presented with slight discomfort from bladder irritation. Urine cultures were positive in four of the patients, and they were treated with antibiotics and increased fluid consumption. Neither migration nor mechanical injury or infection was observed.

Stent exchange was necessary in 12 patients with malignant obstruction after a mean indwelling period of 11 mo (8–14 mo). Cystoscopic findings during stent change did not show any bladder mucosa alterations in the majority of cases. In two cases, bladder erythema and slight bulbous edema around the ureteral orifice were observed. In nine cases of Resonance stent exchange, the

Table 2 – Results of stenting among studied groups

Etiology of ureteral obstruction	No. of patients	Stricture patency rate	Recurrence (no. of cases)
Malignant		Follow-up: 11 mo	
Group A	25	100%	0
Benign		Follow-up: 6.8 mo	
Group B	6	44%	3
Group C	8		1
Group D	4		4
Benign; previously occluded metal mesh stents		Follow-up: 7 d (range: 2–12 d)	
Group E	7	0% (failure)	7

Table 3 – Summary of encrustation evaluation results

Stent no.	Indwelling time, mo	Macroscopic observations	SEM observations	EDAX
Stent 1	12	Distal segment and body: encrustation (Fig. 1a) Proximal: no encrustation	All segments light encrustation (Fig. 1b)	Detected calcium, carbon, phosphorus, oxygen, cobalt, and chromium: calcium oxalate or calcium phosphate (Fig. 1c)
Stent 2	8 (stone former)	Most encrusted segment: bladder end Kinking damage (Fig. 2a)	Encrustation covered kinking damage. The fact that the encrustation edges along the bent portion of the stent were covered by encrustation material suggests that the stent was not damaged during extraction (Fig. 2b)	High concentration of calcium and phosphorus: calcium phosphate (Fig. 2c)
Stent 3	14 (stone former)	Heavy encrustation (Fig. 3a)	Heavy encrustation (Fig. 3b)	Higher peaks at calcium and carbon: calcium oxalate (Fig. 3c)
Stent 4	13	One of the cleanest stents removed; minor encrustation on the loops	Deposits between the coils and material flattening (Fig. 4b)	Limited encrustation; no accurate detection of deposit material (Fig. 4a)
Stent 5	12	Minor encrustation on the loops	The deformities on the stent surface are related to production methods (Fig. 4d)	Sulphur, chlorine, carbon, potassium, phosphorus, calcium, oxygen, and sodium; limited encrustation, no accurate detection of deposit material (Fig. 4c)

EDAX = energy-dispersive analysis by x-ray; SEM = scanning electron microscopy.

advancement of a hydrophilic guidewire parallel to the stent failed because of tight stenosis. Removal of the stent and insertion using a retrograde standard fashion followed. The removal of the stents was uneventful in all cases.

Twelve out of 54 Resonance stents removed displayed encrustation macroscopically, which was more evident at the stent extremities. Five characteristic cases of the studied Resonance stents are presented in Table 3. It was not always possible to detect the encrustation type by EDAX because of very limited deposit material. Pitting on the surface of Resonance stents was related to the production methods used. None of the stents presented corrosion.

4. Discussion

Long-term upper urinary tract drainage required for the relief of ureteral obstruction caused by metastatic retroperitoneal or pelvic malignancy and, less commonly, for the management of benign disease has been an ever-present challenge. We elected to use the Resonance stent because of the high failure rate of polymeric ureteral stents and the influence of nephrostomy in the QoL of patients [1–3,13,14]. The placement of two ipsilateral polymeric ureteral stents in malignant strictures has been reported to perform well in malignant extrinsic obstruction; nevertheless, the Resonance stent has proved to have superior compression resistance over polymeric ureteral stents [10,15–17]. Specifically, a study in pig models that simulated extrinsic ureteral obstruction resulting from malignant disease sufficient to occlude a standard stent showed that the Resonance stent can maintain effective and continuous urine drainage [16]. The Resonance stent has a unique design without end holes: Urine drainage takes place through the tight spiral coil that provides stent flexibility and movement. The latter characteristic allows space to open between coils, which permit fluid access to the lumen. Capillary action may also occur [16].

Borin et al reported the successful clinical use of a Resonance stent in a patient with metastatic breast cancer that was causing retroperitoneal fibrosis. The stent remained patent for 4 mo [10]. Wah et al studied 17 stents in 15 patients with ureteral obstruction caused by malignancy. They reported only three failures, which were probably the result of bulky pelvic malignancy that in turn resulted in high intravesical pressure [11]. Nagele et al managed 18 collecting systems (14 patients) with both benign ($n = 5$) and malignant ($n = 13$) disease with good results. The mean follow-up period was 8.6 mo. The presence of encrustation was reported on two stents. Seven stents were removed because of persistent hematuria, severe dysuria, pain, and insufficient drainage. The selection of a proper stent length was a necessity for patient comfort [12].

In our study, the stricture patency rate in the malignant extrinsic obstruction group after a mean follow-up time of 11 mo was 100%. The latter observation shows that the Resonance stent can resist long-term pressure from extrinsic malignant strictures. The benign disease cases demonstrated a low stricture patency rate of only 44%. In group C, one stent (12.5%) was removed because of heavy encrustation, leading to the assumption that the use of a Resonance stent may have limited indications in stone disease. Moreover, 50% of group B and all group D strictures failed to respond. All stents failed completely in group E cases. In contrast, Nagele et al reported that all stents in the benign disease group remained patent during a mean follow-up period of 11.8 mo, although one was removed because of complications [12]. Nevertheless, the cohort of the above study was different than that presented in this paper. We included cases of ureteroenteric anastomotic strictures, which are difficult cases to manage, even with revision operations, and cases of stone disease, which predispose for stone formation and make an early exchange of stent more likely. Moreover, coaxial insertion of the Resonance stent in ureteroenteric anastomotic strictures containing obstructed metal mesh stents was challenging, and the outcome could not be predicted. In fact, intrinsic proliferative reaction, which was present in the latter cases, was responsible for the early failure of the Resonance stent. Generally, all cases of benign etiology were selected with special consideration for the bothersome nature of the obstructive disease of the patients, which could not be treated otherwise.

Previous studies on the Resonance stent report low rates of complications, including encrustation, pain, irritation, hematuria, and recurrent infections [11,12]. In our cohort, the most common complication was bladder irritation. Neither febrile urinary tract infection (UTI) or stent migration was observed. An analysis of patient height in relation to stent complications by Nagele et al showed a tendency of patients taller than 170 cm to keep the stent for a longer period of time. Proper stent sizing is necessary for patient comfort [12]. During our experience, we used the Resonance stent in different lengths in an attempt to minimize patient discomfort.

The Resonance stent was inserted using both antegrade and retrograde approaches. In the cases of lower or extensive ureteral strictures, the antegrade route through a nephrostomy tract was selected to facilitate placement. In the latter cases, retrograde stent insertion was extremely cumbersome; thus, the antegrade approach was preferred. The right placement of the stent in the upper urinary tract is essential, as there is no retrieval mechanism. Balloon dilatation before Resonance stent insertion was necessary in 35% of patients. Stent exchange was performed using a retrograde approach. Guidewire advancement failed with the stent in situ in nine cases. This failure was the result of the presence of tight stricture around the stent, which could not leave enough space for the wire to be advanced to bypass the stricture. We did not encounter any problems during stent removal.

The Resonance stent achieved stricture patency in difficult cases of malignant obstruction that could not be managed by polymeric ureteral stent insertion because of extrinsic compression. A recent report proves the higher efficacy of the Resonance stent to withstand extrinsic compression than polymeric ureteral stents [15,18]. A nephrostomy would have been an alternative but is related to compromised QoL and morbidity [13,14]. Moreover, the

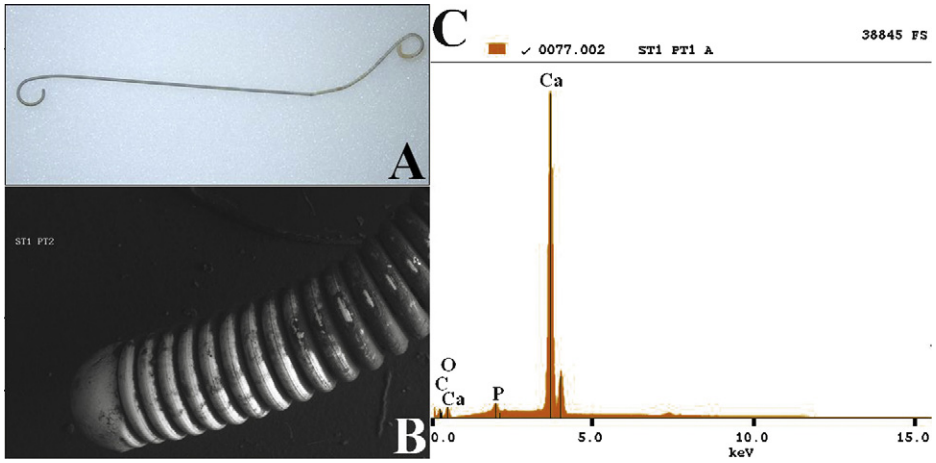

Fig. 1 – (A) Stent 1 with microscopically obvious encrustation on the distal segment; (B) the proximal segment of stent 1, revealing encrustation deposits on scanning electron microscopy; (C) energy-dispersive analysis by x-ray reveals calcium oxalate.

frequent exchange of polymeric ureteral stents, which is associated with morbidity, was avoided. Patients with strictures of benign etiology were not all favored by Resonance stent insertion. Resonance stents were inserted to provide drainage for 12 mo. The cost of a Resonance stent is higher than the cost of a polymeric ureteral stent; nevertheless, the frequent exchange of polymeric ureteral stents increases the cost in terms of material used and services provided. Patient discomfort for the increased number of polymeric ureteral stent exchange procedures should be taken into consideration. The current study is not focused on cost effectiveness but rather investigates the clinical value of a novel stent.

Encrustation was present on all stents. Even if the encrustation was not obvious macroscopically on some stents, SEM and EDAX verified the presence of stone material. Encrustation was evident in 12 out of 54 cases. The absence of corrosion could be attributed to the MP35N alloy, which contains only traces of iron. The only corrosion effect expected was pitting (ie, holes on the surface of the metal structure). The cases presented in Table 3 were selected in an attempt to depict the phenomenon of encrustation in the entire population. Specifically, the latter cases demonstrate the susceptibility to encrustation that could compromise stent drainage potential (Figs. 1 and 2); could show the presence of encrustation on all stents, despite a macroscopically "clean" appearance (Figs. 3 and 4) and could reveal the possible influence of patient history in stenting success with Resonance stents.

To our knowledge, the current study includes the largest patient population treated by Resonance stent insertion. The study contains both malignant and benign cases with a variety of underlying disease etiologies that cause obstruction. Moreover, it is the first attempt at stratification of the

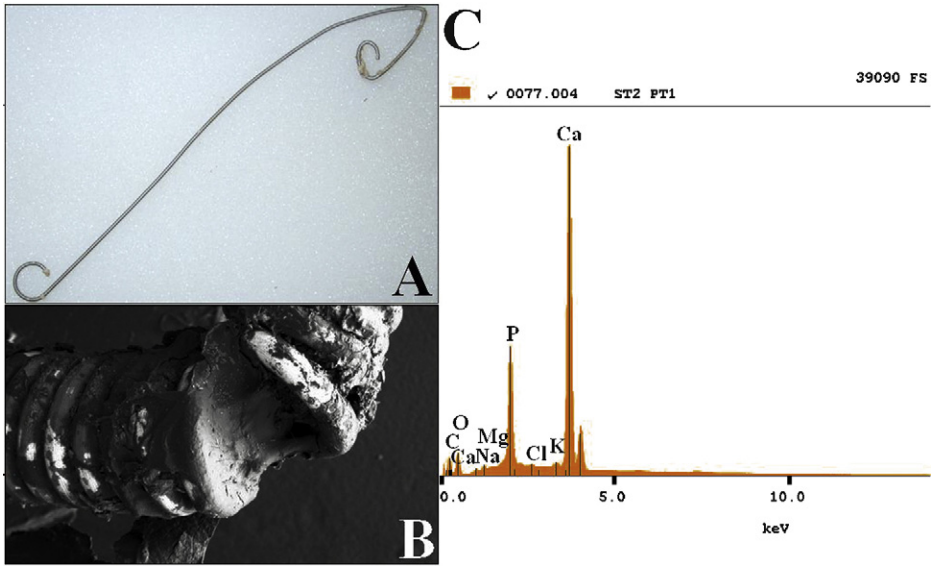

Fig. 2 – (A) Stent 2 with encrustation on both the proximal and distal segments—notice the lesion on the distal segment; (B) the edges of the lesion are covered by encrustation deposits; (C) energy-dispersive analysis by x-ray reveals calcium phosphate.

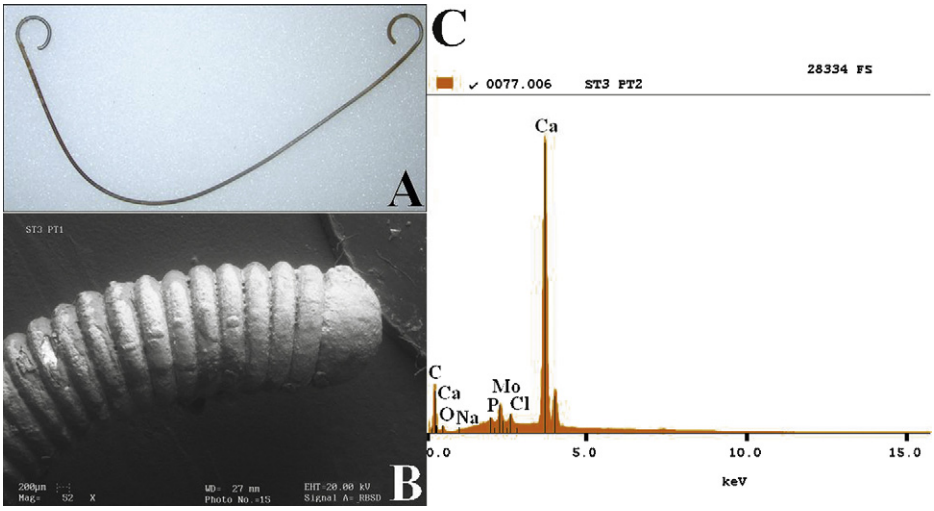

Fig. 3 – (A) Stent 3 has heavy encrustation along its length; (B) encrustation as observed by scanning electron microscopy; (C) energy-dispersive analysis by x-ray shows calcium oxalate.

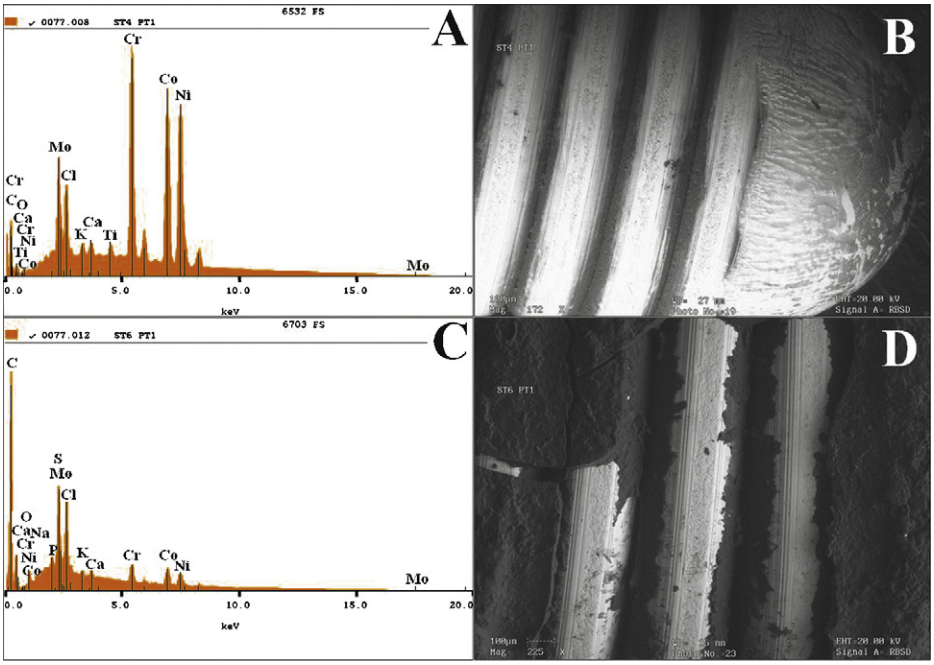

Fig. 4 – (A) No precise detection of the deposits on the stent by energy-dispersive analysis by x-ray was possible (stent 4); (B) scanning electron microscopy revealed encrustation on stent 4; (C) no specific type of encrustation was observed by energy-dispersive analysis by x-ray (stent 5); (D) scanning electron microscopy revealed encrustation and deformities on the surface of stent 5.

indications for Resonance stent use. The stent was inserted using both antegrade and retrograde approaches, a fact that has not been reported before. The methodology for proper selection of the insertion technique has been proposed; however, limitations of the study are the use of morphologic criteria to evaluate stricture patency of the stented ureters while no functional excretory modalities have been performed for the follow-up of the current series of patients. Additionally, the cases in groups B and D were not previously treated by incision to healthy tissue, and the possibility to provide treatment without the use of a Resonance stent was not evaluated.

5. Conclusions

The results of the current study demonstrate that the Resonance stent provides safe and sufficient relief of malignant extrinsic ureteral obstruction. Benign intrinsic proliferative obstructive disease (occluded metal mesh stents in ureteroileal anastomosis) is probably a contraindication for Resonance stent insertion. Benign obstructive disease such as lithiasis or ureteroileal anastomosis strictures could be considered relative indications. Considering the current results, careful selection of cases for stent placement and poststent follow-up is critical to

achieve successful results and to recognize early the potential for stent failure. Further clinical studies are deemed necessary for the clarification of the proper indications for the use of Resonance stents.

Author contributions: Evangelos Liatsikos had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Critical revision of the manuscript for important intellectual content: Liatsikos, Kallidonis.
Statistical analysis: Liatsikos.
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Editorial Comment on: Ureteral Obstruction: Is the Full Metallic Double-Pigtail Stent the Way to Go?

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Stents have become important tools in the hands of modern urologists. Since the first descriptions of long-term indwelling ureteral stents by Zimskind and colleagues in 1967, stents have continuously evolved, especially in terms of design and materials [1]. Ideally, they must have some qualities like biocompatibility, biodurability, high tensile strength, "memory," radiopacity, and varying degrees of softness and firmness [2]. With modern oncologic treatment and survival benefits, urologists have to deal more and more often with ureteral obstruction resulting from malignancy. There is also a search for minimal treatment in cases of benign disease with ureteral obstruction. This is the reason why any novel tool is more than welcome.

Liatsikos et al present an international multicenter prospective study describing the use of the Resonance metallic ureteral stent (Cook Medical, Bloomington, Indiana, USA) in an attempt to clarify the indications for

this novel device [3]. As we can see on the producer's Web site, the Resonance stent is used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction. It must not remain indwelling for >12 mo.

In my opinion, this article could be split into two studies: one with 25 patients to address the recommended malignant, extrinsic etiology of ureteral obstruction, and another with 25 patients to try to extend the indications. In case of malignant obstruction, after a mean follow-up of 11 mo, the patency rate was 100%. The attempt to use the stent off label seems to be problematic, and the stricture patency rate after a mean follow-up of 6.8 mo was only 44%.

As the authors remark, the Resonance stent could be a solution for temporary ureteral stenting of malignant extrinsic obstruction but probably not for benign intrinsic obstructions.

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Malignant extrinsic or benign intrinsic strictures can be managed by JJ stenting. Nevertheless, the rate of failure is high in patients with extrinsic obstruction, and conventional JJ stents are associated with recurrent obstruction and encrustation requiring 3–6 monthly changes [1]. Liatsikos and colleagues assessed a new metallic JJ stent (Resonance) that displays high compressive and tensile strength, making it theoretically recommended for 1-yr duration [2,3]. They demonstrated in a large series of patients that malignant ureteric obstructions were relieved in 100% of patients [2]. The results were less adequate in patients with benign obstruction and clearly were unsatisfactory in patients with obstructed metal mesh stents. Consequently, the authors concluded that careful selection of patients is mandatory, since metallic JJ stents are intended for patients with malignant strictures. In such patients, the mean obstruction relief duration was 11 mo [2], which is significantly better than the results obtained with plastic JJ stents [1].

The cost of metallic JJ stents is 15- to 20-fold higher than that of conventional stents, but the authors did not assess cost effectiveness [2]. The reduction of stent-change frequency is expected to save money, as demonstrated in a study by Agrawal and al, who assessed a shape-memory nickel-titanium alloy thermoexpandable metallic stent [4]. In a series of 55 patients, 28 of whom had malignant strictures, the authors demonstrated that stent duration >8–12 mo compensates for the initial expense –. Such a stent could be an alternative to metallic JJ stents, although its cost effectiveness seems to be slightly lower.

In some cases, metallic stent placement can be impossible due to stricture tightness. In such patients with short life expectancy, palliative subcutaneous pyelovesical bypass remains an effective and well-tolerated alternative to metallic JJ or shape-memory stents [5].

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